reimbursement methods, HTAs at the national level are more common. **CONCLUSIONS:** Basic drivers of market access, such as health care spend, financing structure and regulatory policy create both independent and interdependent mechanisms that support access to new device technologies. Consideration of country level conditions and hurdles will inform device manufacturers' differential strategies to enter established and emerging markets.

PHP196

STAKEHOLDER INVOLVEMENT IN HEALTH TECHNOLOGY ASSESSMENT (HTA) OF NOVEL MEDICAL DEVICES

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HTA for medical devices follows the path of drugs in many countries. There are however substantial differences that should be considered when evaluating medical devices. Drummond (2009) describes six important differences. Medical devices: 1) are often diagnostic therefore requiring to consider their related therapeutic effects; 2) have faster product cycles often making trial results outdated; 3) performance depend on users' skills and complementary investments in training and equipment; 4) innovation may cause a shift from one in-patient setting (operating room) to another (cathlab) or to an out-patient setting with substantial cost-effects; 5) are manufacturer specific, making it difficult to draw conclusions about product class effects; 6) innovation may be difficult to protect with patents thus encouraging imitation with resulting falling prices. In addition to issues 1-6, regulatory approval of a device does not require the same level of evidence as for drugs. Despite initial poor evidence, decisions on health care resource-use based on cost-utility (QALY) need to be made throughout the product lifecycle. This can be achieved by involving stakeholders in regular, timely data exchange for model updating, considering issues 1-6 above. As medical devices directly affect several stakeholders, their respective treatment costs from accounting systems can be used (4). As product registries are continuously updated the improving performance due to new devices and user learning is reflected (2-3). According to regulatory requirements manufacturers must evaluate their product performance and notify competent authorities of adverse events. Such data should update cost-utility evaluations relating to manufacturer specific patient morbidity (5). Furthermore as outcomes data are increasingly captured by devices directly or apps and electronically transferred to electronic health records, the burden on manufacturers to administrate registries may be lessened (2). As medical devices are regularly procured in tenders, their product prices should be used (6). In turn HTA outcomes should inform tenders.

PHP197

OPPORTUNITIES AND LIMITATIONS OF SUSTAINABILITY INDICES IN SATISFYING THE NEEDS OF HEALTH TECHNOLOGY PURCHASERS SEEKING OBJECTIVE AND UNBIASED INDICATORS OF ENVIRONMENTAL AND SOCIETAL IMPACTS

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OBJECTIVE: To establish the extent to which existing sustainability indices provide pertinent and transparent evidence of the environmental and social impacts of health technology providers. **METHOD:** A search was undertaken to identify a comprehensive list of sustainability indices for study. For each of these the following criteria were identified; target constituency, specific environmental or social domains being measured, criteria for inclusion, data sources and ranking or scoring methodology. **RESULTS:** The majority of indices were found to be focused on the needs of investors rather than purchasers. The indices either measured specific environmental or social domains such as carbon efficiency, water risks and social impacts, or provided a broader measure of sustainability by combining environmental, social and governance issues together in a single metric. Incorporation within an index often required inclusion in pre-existing non sustainability criteria against which additional sustainability measures were applied. Data used within the indexes reviewed were found to have been derived from publically available sources such as websites and company reports, or from data submitted by the organisations under evaluation to rating research groups. Few of the indices published a level of methodological transparency that could provide sufficient visibility in order to understand how they are derived. **CONCLUSION:** There remains a latent need among purchasers for a verifiable method of measuring sustainability of providers. In order for a sustainability index to provide utility in the comparison of health technology providers the following criteria must be met; The index should be open to all Health Technology providers, methods used by the index to measure performance should be transparent. None of the current sustainability indexes reviewed fulfilled these criteria. Further study is needed to identify the environmental and social domains of importance to purchasers and the best approach for deriving this data.

PHP198

FROM SCIENCE TO SERVICE: THE ONTARIO PATIENT REPORTED OUTCOMES OF SYMPTOMS AND TOXICITY (ON-PROST) RESEARCH UNIT

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Research suggests that routine collection of Patient Reported Outcome Measures (PROMs) can contribute to clinical decision-making and improve health, but their systematic implementation in Ontario, outside the Edmonton Symptom Assessment (ESAS), has not yet occurred. While ESAS is a valid symptom screening tool, it does not allow customization to disease specific symptoms or toxicities nor does it reflect the multidimensional impact of cancer on physical, emotional and social health. Reaching consensus on a core set of PROMS for each of these domains is critical to improving health and monitoring the impact of cancer. However, applying numerous PROMs is burdensome to patients and evaluators. We are now moving forward to make routine PROM data collection a reality in the cancer system. On-PROST aims to improve the patient experience of cancer and the quality of care through the routine collection of a standardized set of (PROMs) for use in clinical care, and to advance the science of cancer treatment through research across the cancer continuum. Based on initial consensus for the implementation of core PROM data (PROMs-Cancer Core), we will develop a cohesive research agenda and foster the development, standardization and implementation of core PROMs relevant across cancer populations for research use and clinical practice. On-Prost focuses on five cancer research areas: Health Services Research; Biomarker Research; Radiation Oncology; Palliative and Supportive Care; and the PROMs-Cancer Core items. We plan to develop national and international partnerships, and to foster the development, standardization and implementation of core PROMs relevant across cancer populations and for disease specific purposes for routine clinical care and trials. Our goal is to foster common PROMs with multiple purposes, including performance and impact of cancer reporting, that will help deliver personalized quality care and treatment, and will concretely impact on cancer control and policy over the next five years.

PHP199

THE IMPACT OF THE GERMAN PHARMACEUTICAL MARKET REORGANISATION ACT (AMNOG) ON THE GERMAN REFERENCE PRICE MARKET – TRENDS TWO YEARS AFTER THE INTRODUCTION OF THE AMNOG

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With the introduction of the German Pharmaceutical Market Reorganisation Act (**German:** "Arzneimittelmarktneuordnungsgesetz" (AMNOG)) in January 2011, pharmaceutical entrepreneurs have to present a dossier to demonstrate the additional benefit of a new pharmaceutical at product launch in the German market. Pharmaceuticals failing to demonstrate additional benefit against the standard of care in the corresponding indication can be included in an existing reference price group or even trigger the building of a new one. Top-selling reference price markets with many newcomers or price-aggressive competitors are at risk of a repeated examination through the federal joint committee (G-BA) in short intervals, resulting in a frequent updating of the reference price. This triggers a cascade, the so called "Kellertreppeneffekt" (Race to the Bottom), which could result in a rapidly decreasing reference price. One parameter of interest to assure an adequate security of supply is the measure value 160, assuring that at least 20% of packages and 20% of prescriptions are available at a lower price than the new reference price. To avoid the cascade, alternative, lower measure values, such as the measure value 100, can be applied. The measure value 100 is feasible for reference price groups with a large amount of products which are free of patients' copayment. Pharmaceuticals are normally free of patients' copayment if the product price is 30% lower than the corresponding reference price. The focus of our presentation is to analyze the impact of the AMNOG on 10 top-seller reference price groups and to evaluate further adjustments to the reference price level of these groups through varying measure values. Furthermore, additional parameters of interest influencing the reference price level will be considered.

PHP200

EFFECTIVE DEMAND FOR A HEALTH LITERATE HEALTH CARE SYSTEM - EVIDENCE FROM IRISH SURVEY DATA

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Health literacy (HL) research has mainly focused on the skills and abilities of individuals in the health care setting. For the past 20 years, most research has been conducted in North America. However, HL is now gaining political support at European Union level. This presentation is concerned with attitudes that nationally representative survey respondents in Ireland have towards improving their health by seeking a more health literate health care system. Two waves of the Survey of Lifestyle, Attitudes and Nutrition (SLAN 1998 & 2002) were used in this analysis. The primary focus of this study was to look across the socioeconomic gradient and see whether Irish health policymakers should invest in HL as a health inequalities or a public health issue. A secondary objective was to look at preventive health care utilization (General health check-up, blood pressure check-up, blood cholesterol check-up) using the HL variable as the main independent variable stratified by gender and medical card eligibility.

The constructive dependent variable (termed 'effective demand for a health literate health care system') showed that 46% of respondents desired at least one attribute on a health literate health care system. Various multivariate logistic regression models used social class grouping, medical card eligibility, level of education and employment status as the main socioeconomic gradient variables. No discernible trend emerged among the socioeconomic variables. This suggests that HL should be viewed as a public health issue with a policy focus at a system level. Consistently, females (OR 1.15; 95%:1.04 -1.28) were more likely than males to seek a health literate health care system. However, males without a medical card with an effective demand for health literate health care system were more likely to get a general check-up (OR 1.23; 95%:1.03 -1.47). The investment in making the system more user-friendly would benefit all in society and not those stigmatized as having low literacy.

PHP201

CAN RISK MANAGEMENT PLANS (RMP) CONTRIBUTE TO HEALTH TECHNOLOGY ASSESSMENT (HTA) AND KNOWLEDGE OF SAFETY IN EVERYDAY MEDICAL PRACTICE?

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The marketing authorisation of a new medicine is granted on the basis of a favorable benefit-risk balance for its target population and indication. However, not all risks will have been identified at the time when an initial authorisation is sought and many of the risks associated with the use of a medicinal product will only be discovered/fully characterised when the medicine is widely used in everyday medical practice. A full HTA should provide for an evaluation of adverse drug reactions (ADR) including those identified during long term follow- up or which are rare. In addition to knowledge of risks, a relevant consideration for both individual patients and policy makers is the performance of risk minimization measures (RMM) in everyday medical practice. The new European pharmacovigilance legislation embeds the RMP as a key tool in proactive pharmacovigilance. The RMP, as the documented set of pharmacovigilance activities and interventions designed to identify, characterise, and prevent/minimise risks associated with exposure to a medicine, may include specific RMM. RMM should be shown to achieve the desired effect of reducing the burden of ADR and optimising health outcomes. Implementation of RMM may involve a substantial investment of resources and their performance in health care systems should be assessed. In case a RMM proves ineffective, alternative interventions must be identified implemented. We introduce an approach to evaluating the effectiveness of RMM that builds on the assessment of two distinct levels of evidence. The evaluation of the effectiveness of RMM should differentiate between the actual implementation of the RMM, and the attainment of its final objective(s). If the RMM is unsuccessful, this strategy will help to ascertain whether the intervention was inherently ineffective or badly delivered. The assessment requires research encompassing analysis of implementation (process indicators), and traditional epidemiological research addressing the attainment (final outcome indicators) of RMM.

PHP202

BRIDGING THE GAP BETWEEN INSTITUTIONAL LEVELS USING SYSTEMS ANALYSIS

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Transforming the provision of health care involves collaboration and change on many levels. Too often health care delivery decisions are made without considering the complex and dynamic nature of the health system. Approaching these problems from a systems thinking perspective integrates these traits and encourages long term thinking about solutions. Despite being widely used in other disciplines, only recently has systems analysis started to play a larger role in transforming health care provision. The purpose of this work is to outline how systems analysis tools can bridge multiple levels of health care to make more informed decisions. The aforementioned will be illustrated using a Canadian case study. Currently, a provincial strategy to diagnose and treat epilepsy in adults and children in Ontario is being examined. The organization of epilepsy specific care centres (ESCC) into district and regional services is being recommended which will modify current practice patterns and access to care. Subsequently, any changes in delivery will have an impact on referral rates and patterns as well as resource utilization (i.e. beds, staff, and diagnostic tests). The use of systems analysis tools can bring insight into how the inter-relationship between ESCCs can be modeled and how access to care will be affected and aid in capacity planning (i.e. resources and costs).System changes can be graphically illustrated and quantified using the systems analysis tool discrete event simulation. Mapping the clinical pathways and patient flow of epileptic patients through the current system, a simulation model was developed to help inform the planning process. This was useful in understanding how the system might respond and in identifying potential bottlenecks or where resources may be limited. Using discrete event simulation facilitated the ability to take on multiple perspectives by conducting analyses at multiple institutional levels (i.e. government, hospital and health care practitioner).

PHP203

HOW TO OPTIMISE CHANCES FOR SUCCESSFUL AMNOG ASSESSMENTS – BEST PRACTICE APPROACH FOR GERMAN MARKET ACCESS

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Since the introduction of AMNOG in January 2011, manufacturers in Germany are required to submit a "benefit dossier" and show additional benefit in relation to a so-called appropriate comparative therapy to the Federal Joint Committee for every NCE in order to gain access to price negotiations. If an additional benefit is shown, the new reimbursed price will be a surplus on the reimbursed comparator price. Market access in Germany changed significantly due to AMNOG and requires early preparation, an interdisciplinary approach and clearly defined internal processes. Market access strategies and processes have to be reviewed in light of the new framework and adapted in order to optimize the chance to be successful in the AMNOG process. Preparation for AMNOG should start as early as in the planning of clinical studies to implement the right questions into the study and not to rely on surrogate drivers. The FJC will respond best to data providing the most credible scientific clinical evidence. Building RCTs powered to capture such information does present important issues for pharmaceutical companies to address. Early planning of clinical studies should be part of an early strategy development for the NCE that can be informed by early phase modeling of the likely outcome of the benefit assessment. Early identification of the patient groups that are most likely to benefit is vital in order to plan for patient (sub-) populations big enough to achieve statistical significant results and positive outcomes in the AMNOG process. An interdisciplinary approach is required at a stage in the product development where there are no common processes and communication paths established between headquarter and affiliates. A best practice approach requires a well defined process including road maps and checklists per stage of product development in form of standard operating procedures in order to optimize market access.

PHP204

APPROPRIATE METHODS FOR ECONOMIC EVALUATION OF PROGRAMMES WITH COSTS AND EFFECTS EXTENDING ACROSS SECTORS

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Public policies/interventions impact on many areas of activity including areas beyond the main focus of them ; the costs and (dis)benefits falling on other areas of the economy, government and/or private sector, and different individuals. However, there is no consensus on the appropriate way to analyse such policies/interventions to decide which are beneficial and should be implemented. One form of economic evaluation, cost-effectiveness analysis, has been widely used to inform decisions about policies/interventions which affect only a single sector where there is a single agreed output (as in most health care evaluations), however, its use for evaluating interventions with multi-sector impacts is limited. Cost-benefit analysis (CBA), another form of economic evaluation, based on welfarism, has been proposed as a method which allows the evaluation of policies/interventions where costs and benefits fall on several sectors, by aggregating costs and benefits into a given numeraire, normally consumption. However, a key weakness of CBA is it fails to acknowledge the relevance of sectors' budget constraints. This despite the process by which budget constraints are set being viewed as having (democratic) legitimacy. We consider how decisions on policies/interventions with multi-sectoral impacts could most appropriately be informed by economic evaluation. Two options are considered: first, where there is an implied or explicit social welfare function (which could be based on welfarist or extra-welfarist principles); and second, a societal decision making approach. We aim to demonstrate that trade-offs are inevitable and have to be made, but budget constraints cannot be ignored and shadow prices on budget constraints are central no matter which approach is accepted. We also consider whether compensation payments between 'losing' and 'gaining' sectors are a potential means of understanding the net benefit associated with policies with multi-sectoral effects, and whether it is possible, necessary or even appropriate in practice to make such payments.

PHP205

PRIMARY CARE TRANSFORMATION AS A SOLUTION TO THE EPIDEMIC OF CHRONIC DISEASES

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That the world faces an epidemic of chronic diseases is unmistakable. Chronic diseases represent 63% of all deaths worldwide. Against the background of demographic aging, the prevalence of comorbidity or multi-morbidity is as high as 60% among individuals aged 55 to 74 years. In the context of financial crunch wrought by the financial crisis, the financial and non-financial burden of chronic diseases make their management a priority concern globally. Primary care plays a critical role in dealing with this epidemic. To harness the full potential of primary care, however, the way it is organized needs transformation. At present 1) primary care is still organized around the primary care physician even as the shortage of primary care physician is worsening and is unlikely to improve in the immediate future; 2) models of care for the chronically ill are directed to the management of each disease separately, and despite its attribute of continuity, comprehensiveness and patient-centeredness; 3) fails to harness the contribution of patient self-management even as role of patient involvement in their health and health care is recognized; and 4) and overcome the barriers resulting from the structure of the health care system. These challenges are true for primary care in low and middle-income settings and high-income settings. A global framework for the transformation of primary care, consequently, offers promise to every health care system. The critical elements of such involve 1) the development of primary care teams that include physician services extenders such as primary care physicians or nurse practitioners; 2) that will deal with the health needs of the population – rather than the those of the individual patient; 3) by way of engaging chronically ill patients in co-managing their condition; 4) using ehealth technologies and point-of-care-testing facilities.

PHP206

ASSESSING THE VALUE OF ACCESS TO INDIVIDUAL PATIENT DATA FOR REIMBURSEMENT DECISIONS

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To successfully support health care decision-making, cost-effectiveness analysis (CEA) must consider and synthesise all (relevant) available evidence relating to the clinical effectiveness, health-related quality of life (HRQoL) and costs of the health technologies under scrutiny. Evidence based medicine tells us that statistical evidence synthesis of multiple individual patient level data (IPD) sources (e.g. IPD meta-analysis and its extensions) is the gold standard for deriving relative treatment effect estimates, one of the key parameters in any cost-effectiveness model. Unfortunately the evidence base available to the cost-effectiveness modeller is often multifaceted and fragmented, comprising a mix of aggregate (AD, or summary level) and individual patient level data. This scenario poses a series of methodological issues and it is not uncommon for the analyst to end up collapsing the IPD into AD, with consequent loss of information, for use in a standard evidence synthesis model (e.g. meta analysis or mixed treatment comparison of AD). Such a